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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Artavanis-Tsakonas *et al.*

Confirmation No.: 8386

Application No.: 10/781,059

Art Unit: 1647

Filed: February 17, 2004

Examiner: Stoica, Elly Gerald

For: METHODS FOR IDENTIFYING
MODULATORS OF NOTCH ACTIVATION

Attorney Docket No: 7326-132

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b)

MAIL STOP PATENT EXT.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants received a Notice of Allowance mailed July 10, 2009 from the United States Patent and Trademark Office ("PTO") in connection with Application No. 10/781,059 (hereinafter "the '059 application"), together with a Determination of Patent Term Adjustment under 35 U.S.C. 154(b) stating that the projected patent term adjustment to date is 0 days.

Applicants hereby respectfully request reconsideration of the patent term adjustment indicated in the Determination of Patent Term Adjustment under 35 U.S.C. 154(b) ("Determination") mailed July 10, 2009. Specifically, Applicants believe that the patent term adjustment of 0 days is not correct. The correct number of days for the patent term adjustment, for reasons explained below, should be 1,376 days, which is equal to the number of days of PTO delay under 37 C.F.R. § 1.703(a) plus the number of days of PTO delay between the date three years after the filing date to the day that a patent issues on the above-identified application under 37 C.F.R. § 1.703(b) (excluding any overlap in days between the periods defined under 37 C.F.R. §§ 1.703(a) and 1.703(b)), less the number of days of Applicants delay under 37 C.F.R. § 1.704. For the purpose of this Request, Applicants assume that the patent will issue on the above-identified application on April 20, 2010, which is the Tuesday before the date that is four months after the mailing date of the issue fee

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payment, which accompanies this Request. Applicants believe that the patent term adjustment should be a total of 1,376 days.

A request for reconsideration of patent term adjustment under 37 C.F.R. § 1.705(b) must be accompanied by:

- (1) the fee set forth in 37 C.F.R. § 1.18(e); and
- (2) a statement of the facts involved, specifying:
 - (i) the correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment;
 - (ii) the relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) to which the patent is entitled;
 - (iii) whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and
 - (iv)(A) any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704; or
(B) that there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704.

See 37 C.F.R. § 1.705(b).

In support of this request, Applicants submit the following statement of facts:

1. Fee Required Under 37 C.F.R. § 1.705(b)(1)

Pursuant to 37 C.F.R. §§ 1.705(b)(1) and § 1.18(e), the fee required for filing this application is believed to be \$200.00.

Please charge the required fee to Jones Day Deposit Account No. 50-3013.

2. Statement Required Under 37 C.F.R. § 1.705(b)(2)

Pursuant to 37 C.F.R. § 1.702, Applicants submit the following statement of facts in support of this application:

- (i) The correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment are as follows:

1. Correct patent term adjustment:

The correct patent term adjustment is 1,376 days, assuming that the patent on the above-identified application issues on April 20, 2010, which is the Tuesday before the date that is four months after the mailing date of the issue fee payment, which accompanies this Request, which number of days is attributable to (a) the failure of the PTO to mail a notification under 35 U.S.C. § 132 not later than fourteen months after the date on which the '059 application was filed under 35 U.S.C. 111(a) (delay under 37 C.F.R. § 1.702(a)(1)) (the "A period"); and (b) the failure of the PTO to issue a patent within three years of the actual filing date of the '059 application (delay under 37 C.F.R. § 1.702(b)) (the "B period") (minus the number of actual calendar days occurring in both the A period and in the "B period" described below) minus the number of days attributable to the failure of the Applicants to engage in reasonable efforts to conclude prosecution (delay under 37 C.F.R. § 1.704).

2. Bases under 37 C.F.R. § 1.702 for the adjustment:

(a) Delay under 37 C.F.R. § 1.702(a) (the "A period")

The delay by the PTO under 37 C.F.R. § 1.702(a) is 558 days.

As acknowledged by the PTO in its calculation of the patent term adjustment, the PTO failed to mail a notification under 35 U.S.C. § 132 within fourteen months from the date of filing of the '059 application. See PTO's Patent Application Information Retrieval page for U.S. Application No. 10/781,059 at Patent Term Adjustment History ("PTO PAIR Adjustment," Exhibit A). The '059 application was filed under 35 U.S.C. § 111(a) on February 17, 2004. The first notification under 35 U.S.C. § 132 (a Restriction Requirement) was mailed by the PTO on October 27, 2006. Accordingly, the PTO did not mail a notification under 35 U.S.C. § 132 or a notice of allowance under 35 U.S.C. § 151 within fourteen months after the date on which the application was filed (or by April 17, 2005), and thus, the delay under 37 C.F.R. § 1.702(a)(1) is 558 days.

(b) Delay under 37 C.F.R. § 1.702(b) (the "B period")

The delay by the PTO under 37 C.F.R. § 1.702(b) is 1,158 days, assuming that the patent on the above-identified application issues on Tuesday, April 20, 2010, which is the Tuesday before the date that is four months after the mailing date of the issue fee payment, which accompanies this Request.

The '059 application was filed under 35 U.S.C. § 111(a) on February 17, 2004. A patent has not yet issued, however, an Issue Fee payment authorization accompanies this Request. Accordingly, the PTO has not issued a patent within three years of the date on which the application was filed (in this case, February 17, 2007), and thus, the term of the

patent should be adjusted because issuance has been delayed. Assuming that the patent on the above-identified application issues on Tuesday, April 20, 2010, Applicants submit that the period of delay in the B period will be 1,158 days. See 37 C.F.R. § 1.702(b). This delay in issuance of the patent was not included by the PTO in its calculation of patent term adjustment (see “PTO PAIR Adjustment,” Exhibit A).

(c) Overlapping Days in the Delay Periods

According to 35 U.S.C. § 154(b)(2)(A): “To the extent that periods of delay attributable to grounds specified in paragraph (1) *overlap*, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.” See 35 U.S.C. § 154(b)(2)(A).

Applicants submit that there are no calendar days of the A period, discussed in detail below, that were actual calendar days included in the 1,158 days of the B period. Thus, the period of patent term adjustment on a patent that issues on the above-identified patent application is calculated as the sum of (1,158 days minus 0 days) plus 558 days, which is equal to 1,716 days.

Applicants respectfully submit that under controlling case law, calculating the patent term adjustment is the result of summing the number of days of delay under 37 C.F.R. § 1.702(a) that do not comprise actual calendar days occurring in the B period (that is, the A period minus calendar days overlapping in both the A and B periods) and the number of days of delay under 37 C.F.R. § 1.702(b) (the B period). See *Wyeth et al. v. Dudas*, 580 F.Supp.2d 138, 88 U.S.P.Q.2d 1538 (D.D.C. 2008) (hereinafter *Wyeth*), a copy of which is included here as Exhibit B.

In *Wyeth*, the Court held that “the only way that periods of time can ‘overlap’ is if they occur on the same day [and thus, if] an ‘A delay’ occurs on one calendar day and a ‘B delay’ occurs on another, they do not overlap.”

Turning to the ’059 application, the period of delay under subsection (a)(1) of 37 C.F.R. § 1.702 includes the days of April 18, 2005, to October 27, 2006 (558 days). The delay under 37 C.F.R. § 1.702(b) comprises February 18, 2007 to the day the patent on the ’059 application issues. Thus, there are no days under 37 C.F.R. § 1.702(a) that overlap the 1,158 days of delay under 37 C.F.R. § 1.702(b) for the ’059 application, and therefore the total delay under 37 C.F.R. § 1.702 for the adjustment should be a summation of the delays under 37 C.F.R. § 1.702(a) and 37 C.F.R. § 1.702(b), or 1,716 days (the sum of 558 days and 1,158 days), assuming that the patent on the ’059 application issues on Tuesday, April 20,

2010, which is the Tuesday before the date that is four months after the mailing date of the issue fee payment, which accompanies this Request.

(ii) The relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) are as follows:

1. Adjustment under 37 C.F.R. §§ 1.703(a) through (e):

An adjustment is sought under 37 C.F.R. § 1.703(a)(1), which provides, in relevant part, that the period of adjustment is “[t]he number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first.” In particular, Applicants seek to include the delay under 37 C.F.R. § 1.702(a)(1) occurring from April 18, 2005 to October 27, 2006 (558 days) that occurred on different calendar days than the delay under 37 C.F.R. § 1.702(b).

An adjustment is sought under 37 C.F.R. § 1.703(b), which provides, in relevant part, that “the period of adjustment under 37 C.F.R. § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a)...and ending on the date a patent was issued.”

Applicants submit that this period consists of 1,158 days for the period beginning day after February 4, 2007 (the date that is three years after the date on which the '059 application was filed) and ending on the day that a patent issues on the '059 application, assuming that the patent on the '059 application issues on Tuesday, April 20, 2010, which is the Tuesday before the date that is four months after the mailing date of the issue fee payment, which accompanies this Request.

Applicants further submit that 558 actual calendar days of delay under 37 C.F.R. § 1.702(a) do not overlap the any of the 1,158 actual calendar days of delay under 37 C.F.R. § 1.702(b), as explained above.

Accordingly, Applicants’ believe that the delays attributable to the PTO under 37 C.F.R. § 1.702 total 1,716 days, not 558 days as calculated by the PTO.

2. Adjustment under 37 C.F.R. § 1.703(f):

As discussed in section (i) above, Applicants believe that the total delay by the PTO under 37 C.F.R. § 1.702(a) and (b) amounts to 1,716 days. As discussed in section (iv) below, Applicants believe that the number of days of delay attributable to the Applicants

under § 1.704 is 340 days, not 912 days as set forth Determination of Patent Term Adjustment under 35 U.S.C. 154(b) (“Determination”) mailed July 10, 2009. Applicants believe that the total period of adjustment due under 37 C.F.R. § 1.703(f) is 1,376 days, which is the sum of the periods by the PTO calculated under 37 C.F.R. §§ 1.702(a) through (e) (*i.e.*, 1,716 days), to the extent that such periods are not overlapping, less the sum of the periods calculated under Section 1.704 (*i.e.*, 340 days).

(iii) The '059 application is not subject to a terminal disclaimer.

(iv) The circumstances during the prosecution of the '059 application that constitute a failure to engage in reasonable efforts to conclude processing or examination of the '059 application as set forth in 37 C.F.R. § 1.704 are believed to consist of the following:

1. 92 days due to Applicants' filing of a response on November 17, 2004, responding to a Notice to File Missing Parts of Nonprovisional Application from the PTO mailed on May 17, 2004. This response was complete and did not have any omission of any item required by the Patent and Trademark Office that was listed in the Notice to File Missing Parts. Because there was no omission, 37 C.F.R. § 1.704(c)(7) does not apply. Thus, filing on November 17, 2004 “stops the clock” and results in a delay of 92 days, which 92 days is the period from August 18, 2004, which is the day after three months from the mailing date of the Notice to File Missing Parts, to the mailing of the response on November 17, 2004.
2. 74 days due to Applicants' filing of a response on August 25, 2006, responding to a second Notice to Comply With Requirements For Patent Applications Containing Nucleotide Sequences and/or Amino Acid Sequence Disclosures (“second Notice to Comply”). On April 12, 2006, the PTO mailed a first Notice to Comply With Requirements For Patent Applications Containing Nucleotide Sequences and/or Amino Acid Sequence Disclosures (“first Notice to Comply”), to which Applicants filed a response on June 12, 2006. Due to errors in the response filed June 12, 2006, the PTO mailed on June 29, 2006 a second Notice to Comply, to which Applicants filed a response on August 25, 2006, and which response did not have any errors. Applicants believe that in view of the errors in the response filed June 12, 2006, 37 C.F.R. § 1.704(c)(7) applies. In view of 37 C.F.R. § 1.704 (c)(7), the filing of the response on August 25, 2006 results in a

delay of 74 days, which 74 days is the period from June 13, 2006 to the mailing of the response on August 25, 2006.

3. 82 days due to Applicants' filing of a response on April 19, 2007, responding to a non-final rejection from the PTO mailed on October 27, 2006.
4. 92 days due to Applicants' filing of a response on November 29, 2007, responding to a non-final rejection from the PTO mailed on May 29, 2007.

Accordingly, Applicants believe that the delays attributable to Applicants under 37 C.F.R. § 1.704 total 340 days, not 912 days as calculated by the PTO. Applicants believe that the August 25, 2006 entry of "Additional Application Filing Fees" listed in the PTO's Patent Application Information Retrieval page for U.S. Application No. 10/781,059 at Patent Term Adjustment History ("PTO PAIR Adjustment," Exhibit A) is in error. Any and all application and claims fees were authorized to be paid by charging the Jones Day Deposit Account 50-3013 as set forth in the Application Filing Fee Transmittal, which Transmittal was filed on November 17, 2004 as a part of the Response to Notice to File Missing Parts.

In summary, the total adjustment under 37 C.F.R. § 1.702(a) and (b) is 1,716 days, the total delays attributable to Applicants under 37 C.F.R. § 1.704 is 340 days, and thus the total period of adjustment due under 37 C.F.R. § 1.703(f) is believed to be 1,376 days. Accordingly, Applicants respectfully request an adjustment of patent term under 37 C.F.R. § 1.703(f) totaling 1,376 days.

Applicants submit that the issues raised in this request for reconsideration of patent term adjustment are timely raised under 37 C.F.R. § 1.705(b), which provides in relevant part, that "[a]n application for patent term adjustment under this section *must be filed no later than the payment of the issue fee...*" (emphasis added). An Issue Fee Payment Authorization accompanies this Request, hence Applicants submit that the issues raised in this request are timely raised.

Date: October 9, 2009

Respectfully submitted, *by Adriane M. Antler*
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